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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,590	03/27/2006	Satoshi Hibino	287635US0PCT	9725

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER
BADIO, BARBARA P

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
09/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/573,590	HIBINO ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/27/2006; 6/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

First Office Action on the Merits

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 4-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims recite a "use" without setting forth any steps involved in the process and, thus, results in an improper definition of a process, i.e., results in a claim that is not a proper process claim under 35 USC § 101 (see MPEP § 2173.05(q)).

For the purpose of art rejection, the instant claims are assumed to be drawn to compositions comprising the claimed compounds.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because they merely recite a "use" without any active, positive steps delimiting how this use is actually practiced and, thus, it is unclear what process is encompassed by the claimed invention (see MPEP § 2173.05(q)).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,693,629 in view of Thorpe et al. (US 2003/0211075), Glaser (US 4,996,159), Kawanaka et al. (US 5,401,725) or Miyazawa et al. (US 6,608,103).

Hibino et al. teaches progesterone compounds such as 9α-fluoromedroxyprogesterone (see the entire article, especially col. 1, line 56 – col. 2, line

12; Examples 1 and 2). The reference also teaches (a) the compounds are inhibitors of neovascularization and are useful in treating malignant tumors, diabetic retinitis, rheumatism etc. (see for example, Abstract; col. 6, lines 47-52) and (b) various formulations such as tablets, injections and capsules (see col. 6, lines 53-62).

The instant claims differ from the reference by reciting the use of the claimed compounds in the treatment of "ageing macular degeneration". However, the use of inhibitors of neovascularization in the treatment of macular degeneration is well known in the art (see for example, US 2003/0211075, section 0645; US 4,996,159, col. 1, lines 12-29; US 5,401,725, col. 1, lines 23-35; US 6,608,103, col. 1, lines 11-29). Based on the teaching of Hibino and the level of skill of the ordinary artisan in the art at the time of the present invention, the instant claims are rendered obvious.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hibino et al. (US 5,693,629).

Hibino et al. teaches progesterone compounds such as 9α-fluoromedroxyprogesterone (see the entire article, especially col. 1, line 56 – col. 2, line 12; Examples 1 and 2). The reference also teaches (a) the compounds are inhibitors of

neovascularization and are useful in treating malignant tumors, diabetic retinitis, rheumatism etc. (see for example, Abstract; col. 6, lines 47-52) and (b) various formulations such as tablets, injections and capsules (see col. 6, lines 53-62). The compounds and compositions taught by the reference are encompassed by the instant claims.

Note: The recitation of the intended use into a composition claim does not lend patentability to said composition.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibino et al. (US 5,693,629).

Hibino et al. teaches progesterone compounds such as 9α-fluoromedroxyprogesterone (see the entire article, especially col. 1, line 56 – col. 2, line 12; Examples 1 and 2). The reference also teaches (a) the compounds are inhibitors of neovascularization and are useful in treating malignant tumors, diabetic retinitis, rheumatism etc. (see for example, Abstract; col. 6, lines 47-52) and (b) various formulations such as tablets, injections and capsules (see col. 6, lines 53-62).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. However, the scope of the claimed compounds is identical to that of reference and, thus, each of the claimed compound is made obvious by the cited reference.

The instant claims also differ from the reference by reciting the use of the claimed compounds in the treatment of "ageing macular degeneration". However, the use of inhibitors of neovascularization in the treatment of macular degeneration is well known in the art (see for example, US 2003/0211075, section 0645; US 4,996,159, col. 1, lines 12-29; US 5,401,725, col. 1, lines 23-35; US 6,608,103, col. 1, lines 11-29). Therefore, it would have been obvious to the skilled artisan in the art at the time of the present invention to utilize the compounds of the cited reference, which are inhibitors of neovascularization, in the treatment of ageing macular degeneration as recited by the instant claims.

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio, Ph.D./
Primary Examiner, Art Unit 1612